

## REMARKS

Applicant has carefully reviewed the Office Action mailed June 15, 2007 and offers the following remarks to accompany the above amendments.

### Status of the Claims

Claims 1, 5, 7, 9, 11-15, 17-20, 22, 24, and 26-45 are pending in the present application. Claims 2, 4, 6, 8, 10, 16, 21, 23, and 25 were previously cancelled. Claim 1 has been amended to include the limitations of claim 3, and claim 3 is cancelled. Claims 26-45 were previously withdrawn. Accordingly, claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, 24, and 26-45 remain pending.

### Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses.

This rejection stems from the Patent Office's belief that the specification only teaches detecting transitions (peaks and troughs) of heart rate variability (HRV) as opposed to detecting transitions of a natural heart rate cycle provided in the claims (Office Action mailed 6/15/2007, p. 2). Thus, the Patent Office purports that the claims are not supported by the specification. However, the claims as well as the specification provide that biofeedback is based on detecting peaks and troughs of the natural heart rate cycle. Thus, the claims are supported by the specification.

The Applicant believes that the Patent Office's rejection stems from misinterpreting natural heart beat rate variability cycle versus heart rate variability (HRV). As discussed in the specification, a natural heart beat rate cycle is the cycling of natural heart beat rate from a maximum rate to minimum rate as breathing occurs. (¶ 0007) This is shown by example as the heart rate cycle 101 in Figure 1. The natural heart beat rate tends to increase with inhalation occurs, and decreases when exhalation occurs (See ¶ 0007; Fig. 3). HRV is the variation of the natural heart beat rate. That is, the difference between the minimum and maximum heart beat rate in the natural heart beat rate cycle over time. A highly coherent HRV results in consistency in periodicity and amplitude of the natural heart beat rate cycle over time. An incoherent HRV

results from inconsistency in periodicity and amplitude of the natural heart beat rate cycle over time. A coherent HRV is desired.

As discussed in paragraph 0007 of the specification, the inventor recognized that although a heart beat rate cycle has its own natural variable rhythm, there is a strong correlation between a heart beat rate cycle and the breathing cycle. As illustrated in Figure 2, when the natural heart beat rate cycle and breathing cycle are misaligned as shown on the left side of the top graph, the resulting HRV below is highly incoherent. However, when the natural heart beat rate cycle and breathing cycle are aligned, the natural heart beat rate cycle becomes more consistent. This results in a highly coherent HRV as shown in the bottom graph of Figure 2. Thus, providing feedback of the natural heart beat rate cycle transitions can be provided to instruct a patient on aligning their breathing cycle with their natural heart beat rate cycle to achieve greater consistency in a natural heart beat rate cycle and in turn a coherent HRV.

This discussion is also consistent with the remaining teachings of the specification. For example, Figure 4 shows detecting the transitions in the natural heart beat rate cycle. Figure 5 illustrates detecting these transitions with a positive and negative peak rate detection device (507) that detects positive and negative heart beat rate detection from input from the pulse monitor (504). The detection device then provides feedback upon detecting transitions (509).

Because the claims are supported by the specification, this rejection must be withdrawn.

#### Rejection under 35 U.S.C. § 102(b) - Carlson

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,301,499 B1 to Carlson et al. (hereinafter “Carlson”). Applicant respectfully traverses. For the Patent Office to prove anticipation, each and every element of the claims must be present in the reference. Furthermore, the elements of the reference must be arranged as claimed. MPEP § 2131.

Applicant has amended claim 1 of the present application to include the limitations from claim 3. That is, indicating to the human subject, via the second biofeedback signal, a moment to begin inhalation. Further, the claim requires indicating to the human subject, via the first biofeedback signal, a moment to begin exhalation. This is further illustrated by the example in Figure 3. This is provided because the inventor recognized that although natural heart beat rate has its on natural variable rhythm, there is a strong correlation with breathing cycle. (¶ 0007).

By providing instructions on when to inhale and exhale in correlation to the subject's natural heart beat rate cycle, a more consistent heart beat rate cycle is achieved, resulting in a more coherent HRV.

Carlson does not detect transitions in natural heart beat rate cycle like that of the claimed invention. In Carlson, heart beat rates are detected in real time, but are recorded. No feedback of the transitions is provided. Instead the recording is later analyzed to compute averages and a standard deviation (See Carlson, col. 2, ll. 1-10). The Patent Office indicated that Carlson would be withdrawn if the claims indicated that more immediate feedback is provided (Office Action mailed 6/15/2007, pp. 4-5). Although Applicant believes that claim 1 without amendment provided this distinction, and reserves all rights in that regard, claim 1 as amended provides this distinction as well. In the claims, the feedback signals are provided in response to detection of heart beat rate transitions. Thus, this rejection must be withdrawn.

Rejection under 35 U.S.C. § 102(b) - Vaschillo

Claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo"). Applicant respectfully traverses. The standards for anticipation are set forth above.

Vaschillo does not detect transitions of the natural heart beat rate and provided feedback of these transitions like in the claimed invention, because Vaschillo performs spectral analysis that is not in the time domain (Abstract). Vaschillo teaches spectrally analyzing a patient's heart beat and respiratory signals in a passive fashion to generate spectral frequency information for the signals. A phase shift detected in the spectral domain between the heart beat and the respiratory rates are compared and a phase difference is calculated. The phase difference is used to instruct the patient as opposed to detections of transitions in the natural heart beat rate cycle like the claimed invention. Further, because Vaschillo is instructing the patient based on spectral analysis, it also does not indicate to the patient when to inhale and exhale based on the detections of transitions in the natural heart beat rate cycle. Natural heart beat rate is a time-based measurement, thus detecting transitions and providing feedback of these transitions is also in the time domain.

Additionally, the Vaschillo reference does not teach or suggest providing a first and second biofeedback signal to the human subject to indicate that the natural heart rate has reached

the maximum and minimum heart rates, as distinctly claimed. The Patent Office has failed to recognize that claim 1 distinctly claims two biofeedback signals. The single heart rate signal of the Vaschillo reference is not the two biofeedback signals (e.g., the first and second biofeedback signals) which distinctly indicate that the natural heart rate has reached the maximum and minimum heart rates, respectively, as claimed. Accordingly, the rejection of claim 1 based upon the Vaschillo reference should be withdrawn for at least these two additional reasons.

Applicant respectfully submits that the Vaschillo reference does not anticipate claim 1 because multiple limitations of claim 1 are not taught or suggested by the Vaschillo reference. Claims 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

Rejection under 35 U.S.C. § 103(a) – Stabler

Claims 1, 3, 5, 7, 9, 11-15, 17-20, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter “Stabler”). Applicant respectfully traverses. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element can be found in the reference. MPEP § 2143.03.

Stabler does instruct a human to breathe at a target rate based on biological feedback sensors attached to the patient (i.e. human) (col. 2, ll. 35-38). However, Stabler simply displays a graph of heart rate and amplitude of breathing to the patient to indicate to the patient whether the HRV and breathing cycles are synchronized in a feedback fashion. Stabler does not teach or suggest that the instructions include when to inhale and exhale based on transitions in the natural heart beat rate cycle like that provided in the claimed invention. It is left up to the patient to determine when to inhale and exhale. The patient is simply given the results to indicate if the patient is in the “zone” without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heart beat rate cycle (col. 4, ll. 1-17). Stabler simply requires the patient to continue breathing in a controlled fashion until the patient gets it right and reaches the “zone.” A breakthrough in the Applicant’s invention is the recognition of inhalation and exhalation in breathing cycle to coherence and instructing the patient specifically at the

transitions times as to when to inhale and exhale. Thus, Stabler does not render the claimed invention obvious, and this rejection must be withdrawn.

Claims 5, 7, 9, 11-15, 17-20, and 22 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, and 22 should be withdrawn for at least the same reasons as claim 1. Applicant respectfully submits that claims 1, 5, 7, 9, 11-15, 17-20, and 22 are in condition for allowance and notice of the same is requested at the earliest possible date.

Conclusion

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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